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Contemporary challenges on access to medicines: beyond the UNSG High-Level Panel

Desafios contemporâneos no acesso a medicamentos: para além do painel de alto nível do Secretario Geral das Nações Unidas

Jorge Bermudez [1]

Abstract *Within the context of the recently released United Nations Secretary-General´s Report of the High-Level Panel on Access to Medicines, the author reviews issues related to the context and discussions on access to medicines and the conflict between trade and health during the last decades. These issues have been relevant and outstanding in Global Health, especially questioning the current system of innovation, R&D and IP protection. Lessons learned from the HLP Report are highlighted and the need to further discuss and implement concrete actions, as the world has moved from the MDGs to the SDGs, demand strong actions derived from the United Nations and a strong interaction with other key stakeholders. Affordability and unaffordability of new technologies are discussed, making clear that we need to implement bold actions in order to ensure access to medicines as a human right.*
Key words *Health policies, Access to medicine, Global health*

Resumo No contexto do Relatório do Painel de Alto Nível em acesso a medicamentos do Secretario-Geral das Nações Unidas, relatório recém liberado, o autor revisa questões relacionadas ao contexto e discussões sobre o acesso a medicamentos e o conflito entre saúde e comércio presente nas últimas décadas. Estas questões tem sido relevantes na Saúde Global, em especial questionando o atual sistema de inovação, P&D e proteção da propriedade intelectual. As lições aprendidas do Relatório do Painel de Alto Nível são destacadas e a necessidade de discutir com maior profundidade e implementar ações concretas, com o mundo mudando dos ODMs para os ODSs, exige ações fortes por parte das Nações Unidas e uma forte interação com outros atores chaves. A capacidade de aquisição de novas tecnologias, ou incapacidade, são discutidas, deixando claro que precisamos de implementar ações corajosas para assegurar o acesso a medicamentos como um direito humano.
Palavras-chave *Políticas de saúde, Saúde global, Acesso a medicamentos*

[1] Escola Nacional de Saúde Pública, Fiocruz. R. Leopoldo Bulhões 1480, Manguinhos. 21041-210 Rio de Janeiro RJ Brasil. jorge.bermudez@fiocruz.br

Precedents

When the United Nations Secretary-General turned public the Report of the High-Level Panel set up ten months before[1], the world realized that he had just unleashed a new chapter of a major polemic that was being discussed more than ten years before the report, moving back and forth in all the recent forums related to Global Health. Last November 2015 the UN Secretary-General announced the nomination of a high-Level panel on access to medicines, with 16 members and two former Heads of State as Co-Chairs, with the incumbency of discussing the failures on accessing medicines and health technologies to ensure health and well-being, affecting people and governments in both poor and rich countries. The panel was to make recommendations aiming to remedy the policy incoherence between international human rights law and trade rules in the context of access to health technologies in order to seek achievement of a better balance, all this linked to the Sustainable Development Goals and ensuring to leave no one behind. This was acknowledged as the demonstration of the relevance of this issue, having been pushed directly to the core of the United Nations and not restricted to the World Health Organization as had been for the last twenty years.

In a previous publication[2], we revised that, although since 1975, WHO was strongly advocating issues related to Medicines Policies, the concept of Essential Medicines and Rational Use of Medicines especially within primary health care, it was an intensified debate since 1998, when the World Health Assembly was called to discuss the so-called "Revised drug strategy". Within the WHO, for the first time trade and health were explicitly confronted, or rather the consequences of trade and trade agreements on health, public health and access to medicines. This issue was thoroughly discussed and approved one year later as a WHA Resolution, for the first time introducing, within WHO, the WTO TRIPS Agreement and its impact on health[2-4].

That period and the discussions have been overviewed in previous publications, always stressing the complementarity between the public and the private sectors ensuring access to medicines, focused primarily on essential medicines, also ensuring efficiency on the financing, rational use and the quality of products[5,6].

Triggered by the WHA Resolution on the "revised drug strategy" approved in 1999 (WHA52.19), we can consider that the issue of access to medicines was emphatically introduced within the WHO agenda dealing with the impact of trade with yearly discussions since 2001and beyond, including resolutions related to this issue, among them: WHO medicines strategy (2001); Ensuring accessibility of essential medicines (2002), taking into account the WTO TRIPS Agreement signed in 1994, the Millennium Development Goals and the Millennium Declaration in 2000 and the landmark represented by the Doha Ministerial Declaration on the TRIPS Agreement and Public Health signed by all the WTO members also in the year 2000.

Therefore, we can be assured that the issue of access to medicines and, further, access to health technologies, has been set up high on the global health agenda, as can be seen by the different and several forums that have discussed that issue during the last years and decades[7-10].

Access to medicines on the global agenda

Several publications have reviewed the concept of "access to medicines" and its different dimensions[11-15]. It is clear that multiple factors affect access to medicines. Special interest has been raised related to factors that define costs and pricing of medicines in different markets, as they represent barriers to access. Limited competition, market failures, monopolies and oligopolies are some of the factors that determine limitations on access, accessibility and especially affordability. Of special interest globally, the main barriers identified on access to medicines include intellectual property issues, regulatory issues and the high prices of new medicines, not necessarily related to high production costs, but invariably linked to the long-term monopolies resulting from patent protection.

Effectively, access to medicines has been on the global agenda very strongly during the last decade, advocating greater international cooperation to eliminate inequities, including the elimination of the high costs of medicines that especially in many low and middle-income countries, have to be beared by the population. Therefore, the advocacy for local production also has to be supported and made reality[16]. The impact of international, regional or bilateral trade agreements also has been discussed and the need to uphold the right to health during the discussions and negotiations[7].

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What lessons have we learned from the HLP?

The first reference of the United Nations to the issues of the WTO TRIPS Agreement and access to medicines was since the issuing of the 1999 United Nations Development Program (UNDP) on Human Development. The 1999 report mentioned the potential downsides of this IP regulatory framework for developing and least developed countries, pointing that the costs of maintaining this system could outweigh the benefits for these countries[17,18].

Nevertheless, the United Nations Secretary-General High-Level Panel on Access to Medicines (www.unsgaccessmeds.org) has endeavored a ten-month process that has been very rich in discussions, views, convergence and divergence, but especially on the issue of pointing to a new reality that may be consensual worldwide. So what lessons have we learned during this intense debating process, which plunged the members from New York to London and Johannesburg, besides spurring actions, movements, contributions and positioning during the public forums and opportunities created for discussion?

The HLP Report, which all the panel members have approved the final version, may be considered a great advance in many ways. Initially, it raises the issue of access to medicines and human rights to the top management of the United Nations and no longer restricted to the Health agencies and especially WHO. Indeed, the first recommendation has spelled that all "WTO members should commit themselves, at the highest political levels, to respect the letter and the spirit of the Doha Declaration on TRIPS and Public Health...".

Additionally the issue of access to medicines and health technologies is no longer considered as a problem or threat restricted to low and middle-income countries, but is a problem that affects all human kind and also not restricted to a group of diseases. We are no longer dealing with AIDS, TB and malaria or with the so-called Neglected Tropical Diseases, but with all diseases that affect human kind all over the world, including chronic non-communicable diseases.

It has ensured a human rights approach in the core of the discussions and also, notwithstanding discrepancies, has challenged a broken pharmaceutical system based on patent protection and monopolies, therefore hampering competition and lowering of the high prices always present with new products entering the market. At the same time, the delinkage between the costs of R&D and the final pricing of medicines will surely advance on the direction of a global initiative.

The WTO TRIPS Agreement has been exhaustively discussed and agreement has been conveyed on the issue of the rights of WTO members to issue TRIPS flexibilities as a sovereign right and undue pressures on TRIPS-plus measures within trade agreements must be halted and even penalized. Diverse examples of TRIPS-plus provisions contained in trade agreements have been highlighted in the report, explaining what are the consequences of the provisions on health.

A Box within the panel report gives a snapshot of the TRIPS Agreement flexibilities with the explanation of each one of them and the article that refers to it. The Doha Declaration on the TRIPS Agreement and public health has been reassured as a strong and vital instrument to ensure the right of countries promoting access to medicines. Another Box of the report includes the Doha Declaration with its seven important articles.

It is important to highlight that a Box has been included mentioning the current obstacles to the use of the TRIPS flexibilities, with two outstanding and concrete examples. One comes from Thailand, when in 2006 decided to import from India generic versions of Efavirenz, an antiretroviral, under compulsory license, with high hostility from the manufacturer of the innovator and support from the USA Government, questioning the legality of the compulsory license and pressuring the revocation of Thailand's decision. The second example coming from Colombia is one that we need to analyze very much profoundly, as letters to the Co-Chairs of the HLP have been motivating a permanent discussion, as they accused various domestic and foreign parties to dissuade and pressure the Colombian Government from declaring public interest for the use of imatinib to treat leukemia. This medicine has been included on the WHO Model List of Essential Medicines and all efforts were due to ensure affordability of the product. The multiple letters from Colombia included and mentioned within the HLP report even were addressed at the extreme positions of hampering the Peace Treaty that is currently being discussed in Colombia, giving an end to decades of violence and millions killed during these confrontations.

Transparency and governance were very present issues in all the process and R&D development. Additionally, we have stressed the positive role of civil society not only on advocacy issues, but also contributing by large on technical and

legal issues related to IP and access to medicines, highlighting but not restricted to patent oppositions where national laws so ensure.

The way beyond the UNSG High-Level Panel

As we move from the Millennium Developing Goals towards the Sustainable Developing Goals and post-2015, we have to make sure that no one is being left behind, as millions have been left behind previously. On that premise, we have welcomed the United Nations Secretary-General on his great leadership on highlighting the need to discuss and remedy political incoherence present between individual rights and collective rights, between health and trade, between innovation and public health. This has been the tonic of all the discussions, public hearings and consultations that have inspired the UNSG High-Level Panel on moving forward and approving the HLP Report that has been made public last September 2016.

As discussed previously, a lot has been achieved on the issues of remedying and moving forward to ensure that all people have access to life-saving technologies worldwide. Nevertheless, affordability still remains as a threat and a barrier to people and also to national health systems, as well as international organizations that deal with strengthening health systems and delivering technologies to people in need. In all forums, we have to state clearly that we cannot continue with a narrow scope of diseases or addressing only low and middle-income countries, but address all diseases and move the terminology from neglected diseases to neglected populations[19,20].

As included in the HLP Report, we have addressed several Commentaries in the Annex 1. They do not necessarily mean that the Report is not addressing the main issues that we have been discussing. It simply means that we could have been more bold and gone further on issues related to ensuring access to medicines for those in need. As has already been discussed before[21], the panel has not been able to agree on the systemic failure of the current R&D and access system, which we are sure will continue to be discussed and further worked. After receiving over 180 submissions and the public hearings held in London and Johannesburg, we consider that the panel could have been bolder addressing proposals that will surely call on new regimes for pharmaceuticals, as has been challenged in advance.

Affordability and unaffordability of new technologies will continue to hamper access, both in the North and in the South. The HLP Report spells on Hepatitis C new Direct Acting Antivirals and Oncologic products, which are unaffordable worldwide. High prices all over the world of patent protected medicines will continue to represent a barrier to access[22-26]. Voluntary licenses are simply not enough, not sustainable and always carry a limited geographic scope, not necessarily linked to the disease burden. If access to medicines is to be considered an essential human right, further than voluntary and compulsory licensing, the current IP system must be profoundly discussed and changed.

Patentability criteria are a subject related to national legislation, of course in compliance with the WTO TRIPS Agreement. Therefore, we have supported that Governments must be enabled to address access barriers on a first step within the current IP system by pursuing effectively automatic compulsory licensing for essential medicines. This proposal is aligned with a submission received and discussed by the HLP, with legal knowledge and support. Based on the WHO Essential Medicines concept and the WHO Model List of Essential Medicines, which is regularly updated, a first approach can be the establishment by national governments of effectively automatic non-voluntary licensing of patents related to the medicines within the WHO Model List and expanding to each countries' own Essential Medicines lists. This proposal is compliant with the TRIPS Agreement and the Doha Declaration on TRIPS and Public Health, as each WTO Member "has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted". A stronger interaction between the UN and WTO would identify IP barriers and guide countries on realigning the obligations under human rights treaties and trade. This approach moves further in addition to the UNSG HLP Report and surely will accelerate the necessary response on the Sustainable Development Goals and making sure that no one is being left behind on the quest to ensure the right to health in all places and all ages.

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